



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

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November 29, 1985

#19

Mr. Ronald Wilson
Health Assessment Policy Staff
Office of Health Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U. S. Patent No. 4,224,946, issued September 30, 1980, was filed on November 25, 1985 under Title II of Public Law 98-417.

The assistance of your Office is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC 156 (g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC 156(d)(2)(A). However, our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 USC 156. Note that the subject application relates to the same approved product as the application for patent term extension of U.S. Patent No. 4,246,904, but that an extension is requested depending on the results of pending litigation.

C.E. Van Horn

Charles E. Van Horn
Director, Group 120
U. S. Patent and Trademark Office

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